mintmedical

RANO 2.0
Protocol Abstraction Worksheet

This worksheet is a structured tool designed to support the abstraction of protocol-specific parameters for clinical trials implementing RANO 2.0 Response Assessment Criteria. Because RANO 2.0 involves disease-specific implementations and permits protocol-defined adaptations, the primary study protocol must be reviewed to determine the specific tumor type, lesion measurement requirements, response categorization, and rules for progression confirmation.

This document provides a standardized framework to capture these elements, ensuring that response assessments are conducted consistently and align with both general RANO 2.0 guidance and individual study specifications.

INSTRUCTIONS FOR USE

1. **Reference the Protocol**
   Keep the primary clinical study protocol available while completing this form.
2. **Document Adaptations**
   Record any protocol-specific adaptations or deviations from standard RANO 2.0 in the designated fields.
3. **Utilize During Trial Planning**
   Use this worksheet as a reference guide when planning your RANO 2.0 study to facilitate communication on study objectives and the related response assessment.

DISCLAIMER

This worksheet is a supplementary administrative tool. It does not replace the official study protocol or the primary RANO 2.0 publications[1,2]. Always defer to the study-specific protocol for definitive assessment criteria.

[1] Wen PY, et al. RANO 2.0: Update to the Response Assessment in Neuro-Oncology Criteria for High- and Low Grade Gliomas in Adults. J Clin Oncol. 2023;41:5187–5199.

[2] Ellingson BM, et al. A Neuroradiologist's Guide to Operationalizing the Response Assessment in Neuro-Oncology (RANO) Criteria Version 2.0 for Gliomas in Adults. AJNR Am J Neuroradiol. 2024;45(12):1846–1856.

Section	Parameter	Protocol Specification (complete this section)	Notes/Guidance Examples
Study Information	Study ID / Protocol Number		
	Tumor Type	**Type:** ☐ Contrast enhancing ☐ Non-Contrast enhancing ☐ Mixed enhancement ☐ Other, specify:	*Refer to the protocol to identify the tumor types and refer to the RANO 2.0 publication for details on enhancing/non-enhancing qualifiers such as HGG, LGG, IDH-wildtype Glioblastoma (GBM), IDH-mutant Astrocytoma (Grades 2-4) with substantial non-CE tumor, etc.*
	Patient Population		*e.g., Newly diagnosed vs recurrent*
	Treatment Type		*e.g., Immunotherapy, cytotoxic therapy, radiation, device*
	Imaging Modalities		*e.g., MRI required (standard for RANO)*
Lesion Selection	Maximum # Enhancing Target Lesions		*Typically a maximum of 3 Target lesions if Enhancing only. If Mixed tumor type, typically a maximum of 2 Enhancing Target Lesions and 2 Non-enhancing Target Lesions.*
	Maximum # Non-Enhancing Lesions		*Typically a maximum of 3 Target lesions if Non-enhancing only. If Mixed tumor type, typically a maximum of 2 Enhancing Target Lesions and 2 Non-enhancing Target Lesions*
	Minimum **Target** Lesion Size for Measurement at baseline		*e.g., 10.0 mm in LDi and SDi*
	Minimum Measurable **New** Lesion Size for Measurement when first identified at follow-up		*e.g., 10.0 mm in LDi and SDi*
	Minimum **size increase** for non-measurable non-target or new lesions to be considered in Tumor Burden Sum Calculations		*e.g., ≥ 5.0 mm increase in LDi and SDi and become measurable (≥ 10.0 mm in LDi and SDi) to be included in Tumor Burden Sum Calculations* *Non-Target lesions and New lesions are included in the Target lesion sum of 2D PPD when they increase in size and become measurable*
Measurement Methodology	Measurement Type and Sum Calculation	☐ PPD/SPPD ☐ VOL/SOV	*Most RANO 2.0 implementations use PPD; Volumetrics may also be reported for exploratory analysis*
	Baseline Reference		*Usually first post-radiotherapy MRI*

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Response Assessment	Overall Response Categories (select all that apply)	☐ Complete response ☐ Major response ☐ Partial response ☐ Minor response ☐ Stable disease ☐ Progressive disease ☐ Not Evaluable	*Protocol defined*
	Response Confirmation Required	☐ YES ☐ NO	*Most protocols require confirmation of CR/PR*
	Response Confirmation Interval	**Interval:**	*Often ≥4 weeks*
	Progression Assessment-Preliminary PD Allowed	☐ YES ☐ NO	*Often required for pseudoprogression scenarios*
	Progression Assessment-PD Confirmation Required	☐ YES ☐ NO	*Follow-up scan required to confirm PD*
	Progression Confirmation Interval	**Interval:**	*Often 4–12 weeks or N/A*
	Progression Pseudoprogression Interval	**Interval:**	*Often first 12 weeks after radiation or N/A*
	Progression Pseudoprogression PD within window	☐ YES ☐ NO	*First PD is preliminary PD and Confirmation required*
	Progression Clinical Deterioration	☐ YES ☐ NO	*Can confirm PD early; Yes if clinical determination overrides other disease status*
Clinical Status	Clinical Status will be utilized in response assessment	☐ YES ☐ NO	*Determine if radiological evaluation only **or** if clinical status will be part of response assessment*
	Clinical Deterioration Defines PD	☐ YES ☐ NO	*Without imaging progression*
Corticosteroid Evaluation	Steroid Use reported and will be utilized in response assessment	☐ YES ☐ NO	*Determine if radiological evaluation only **or** if corticosteroids will be part of response assessment*
	Steroid Change Considered in Response		*e.g., Must be stable or decreasing for CR/PR*